

### REMARKS

Favorable reconsideration of this application, in view of the present amendments and in light of the following discussion, is respectfully requested.

This Amendment is submitted in accordance with 37 C.F.R. § 1.116, which after Final Rejection permits the entry of amendments cancelling claims, complying with any requirement of form expressly set forth in a previous Office Action or presented rejected claims in better form for consideration on appeal. It is believed that the present Amendment places the claims in condition for allowance without requiring further search and/or consideration. Therefore, it is respectfully requested that the present Amendment be entered under 37 C.F.R. § 1.116.

After entry of this Amendment, Claims 1, 20, 27-38, 34, 67 and 69-71 are pending. Claims 1 and 67 are amended to further clarify the features contained therein, and Claim 3 is canceled without prejudice or disclaimer. No new matter is introduced.

In the outstanding Office Action, Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 were rejected under 35 U.S.C. § 112, first paragraph; Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 were rejected under 35 U.S.C. § 102(a) and/or 35 U.S.C. § 102(e) as being anticipated by Yu (U.S. Patent Application Publication No. 2003/0105496); and Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 were alternatively rejected under 35 U.S.C. § 103(a) as being unpatentable over Yu.

Initially, Applicant gratefully acknowledges the courtesy of Examiner Kahelin in holding a personal interview with Applicant's representative on May 18, 2010. During the interview, the outstanding issues in this case were discussed, as summarized herein and in the Interview Summary, which the Examiner has made of record. Specifically, Applicant's representative explained how the claims of this application conform to the requirements of 35 U.S.C. §112, first paragraph, and how the applied references fails to disclose every feature of

recited in the claims. No agreement was reached pending further consideration and/or search by the Examiner.

With respect to the rejection of Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 under 35 U.S.C. § 112, first paragraph, this rejection is respectfully traversed as non-limiting support for delivering stimulation to only a left ventricle of the heart can be found at least at paragraph [0057] of the specification. As pointed out in previous responses, this paragraph describes the benefits of pacing only the left ventricle and explains how this pacing is established with reference to Figure 4.

The Office is respectfully reminded that M.P.E.P. § 2163.04 states that the written description requirement of 35 U.S.C. § 112, first paragraph, is met, unless one of ordinary skill in the art would not recognize in Applicant's disclosure a description of the invention defined by the claims. As such, it is believed that a person of ordinary skill in the art would recognize delivering stimulation to only a left ventricle of the heart from at least these descriptions in the specification. Accordingly, it is believed that Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 conform to the requirements of 35 U.S.C. § 112, first paragraph, and it is respectfully requested that the rejection of these claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

If, however, the Examiner continues to disagree that Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 conform to the requirements of 35 U.S.C. § 112, first paragraph, it is respectfully requested that the Examiner provide a showing of substantial evidence, why a person skilled in the art would not recognize in the present disclosure a description of positioning at least one second electrode of the signaling electrodes at a position in the right ventricular septum to deliver stimulation to the left ventricle as defined by the claims.<sup>1</sup>

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<sup>1</sup> MPEP § 2163.04.

With respect to the rejection of Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 as being anticipated by Yu, Claim 1 is amended to recite, *inter alia*, a method of configuring signaling locations within a heart for performing intrachamber resynchronization, where the method includes:

positioning signaling electrodes to deliver stimulation to only a left ventricle of the heart, the signaling electrodes being positioned along a first and second axis interior to the heart, the second axis extending within the left ventricle to position at least one first signaling electrode of the signaling electrodes thereabout, *the first axis extending into a right ventricular septum of the heart to position at least one second signaling electrode of the signaling electrodes at a position in the right ventricular septum to deliver stimulation to the left ventricle...*(Emphasis added.)

The applied reference, Yu, describes a method of synchronization of ventricular wall contraction using direct mechanical measurements.<sup>2</sup> In this regard, Yu illustrates an accelerometer (142) and an electrode (140) positioned at a free wall of the left ventricle (112), an accelerometer (150) and electrode (148) positioned at a free wall of the right ventricle (108), and an accelerometer (146) and electrode (144) positioned within the right ventricle adjacent to the septum (109).<sup>3</sup> In operation, Yu describes that the accelerometers (142, 146 and 150) move with corresponding ventricular wall contractions and generate corresponding signals, which are used by a processing module (198) to generate stimulating signals delivered to electrodes (148, 144 and 140) to ensure optimal synchronization.<sup>4</sup>

However, Yu does not describe that the electrode (144) is positioned in the right septum (109) to stimulate the left ventricle. Instead, Yu illustrates that the electrode (144) is positioned within the right ventricle (108) next to the septum (109), and is silent as to any left

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<sup>2</sup> Yu at paragraph [0013].

<sup>3</sup> Yu at paragraph [0027] and Figure 3.

<sup>4</sup> Yu at paragraphs [0032]-[0033].

ventricle stimulation caused by this electrode.<sup>5</sup> Conversely, amended Claim 1 recites that the first access extends into a right ventricular septum of the heart to position at least one second signaling electrode of the signaling electrodes at a *position in the right ventricular septum to deliver stimulation to the left ventricle*. As noted in the declaration of Dr. Morton Mower, M.D. submitted as Exhibit A with the response filed January 21, 2010, “it has never been widely appreciated that in the mid-septum the right ventricular endocardium is particularly thin, and the surface of the right side of the septum is functionally left ventricle.”<sup>6</sup> Thus, the mere placing of an electrode in the right ventricle septum without more does not necessarily result in left ventricle stimulation. Yu, however, is silent as to the exact positioning of the electrode (144); much less that electrode (144) is positioned on the right ventricular septum to stimulate the left ventricle. As can be appreciated by the Office,

“A claim is anticipated **only if each and every element as set forth in the claim is found**, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The **identical invention must be shown in as complete detail as is contained in the ... claim**.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (Emphasis added.)

Therefore, Yu is deficient relative to Claim 1 at least with regard to the positioning of the second electrode. As such, Yu it is submitted that does not anticipate Claim 1 or any claim depending therefrom. Accordingly, it is respectfully requested that the rejection of Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 under 35 U.S.C. § 102(a) and § 102(e) be withdrawn.

As to the rejection of Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 as being obvious over Yu, this rejection is respectfully traversed.

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<sup>5</sup> See Figure 3 of Yu.

<sup>6</sup> See the declaration of Dr. Morton Mower, M.D. submitted January 21, 2010 at item 13.

In support of its *prima facie* case of obviousness relative to the claims of this application, the outstanding Office Action relies on the declaration of Dr. Morton Mower, M.D. to asserts that “as applicant apparently considers the septal electrode of Figure 4 to deliver stimulation to only the left ventricle, Yu’s septal electrode 44 likewise delivers stimulation to only a left ventricle,”<sup>7</sup> and that “declarant takes the position that pacing the right ventricular septum is pacing only the left ventricle because this surface is functionally the left ventricle.”<sup>8</sup> However, such assertions rely on a misreading of Dr. Mower’s declaration.

To be clear, item 13 of the Dr. Mower’s declaration states that “the septum separating the left and right ventricles *consists of a mixture of left and right ventricular endocardium*,” and that the “ratio varies in the various parts of the septum, and when the septum is paced, it *most often* results in a *delay* in left ventricular activation.”<sup>9</sup> Thus, contrary to the assertions in the outstanding Office Action, Dr. Mower’s declaration states that because the ratio of right endocardium to left endocardium varies throughout the septum, pacing most often results in delayed activation of the left ventricle. Dr. Mower also declares that “it has never been widely appreciated that in the mid-septum the right ventricular endocardium is particularly thin, and the surface of the right side of the septum is functionally left ventricle.”<sup>10</sup> Thus, contrary to the assertions in the outstanding Office Action, pacing of the left ventricle through the right ventricular septum occurs when the electrodes are located in *a particular position*, which is not widely appreciated.

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<sup>7</sup> See the outstanding Office Action at pages 6-7.

<sup>8</sup> See the outstanding Office Action at page 4, item 5.

<sup>9</sup> See the Declaration of Dr. Mower at item 13 (emphasis added).

<sup>10</sup> Id.

The outstanding Office Action relies on this misinterpretation of Dr. Mower's declaration to in essence assert that stimulation of the right ventricular septum is inherently stimulation of the left ventricle.<sup>11</sup> However,

To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily** present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may **not** be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added) (citation omitted) (quoting *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991)).

As discussed above, Dr. Mower's declaration states that the location on the right ventricular septum at which left ventricle stimulation *has never been widely appreciated*. Therefore, the inherency assertion of the Official Action is incorrect, and unsupported.

Consequently, it is submitted that a *prima facie* case of obviousness relative to Claims 1, 3, 20, 27, 28, 34, 67, and 69-71 has not properly been made. Accordingly, it is respectfully requested that the rejection of Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 under 35 U.S.C. § 103(a) be withdrawn.

For the reasons discussed above, no further issues are believed to be outstanding in the present application, and the present application is believed to be in condition for formal allowance. Therefore, a Notice of Allowance for Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 is earnestly solicited.

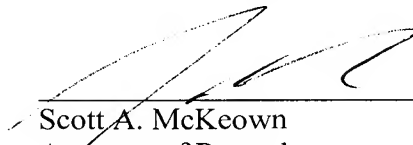
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<sup>11</sup> See the outstanding Office Action at page 8.

Should, however, the above distinctions be found unpersuasive, Applicant respectfully requests that the Examiner provide a detailed explanation via Advisory Action under M.P.E.P. § 714.13 specifically rebutting the points raised herein.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, L.L.P.



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Scott A. McKeown  
Attorney of Record  
Registration No. 42,866

Customer Number

**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 08/09)

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